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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/596,101	06/16/00	DE BAETSELIER	P 4432US

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ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/596,101	DE BAETSELIER ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on th cover sheet with th corresp ndence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4-10, 12, 14-15 and 18-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11,13,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, claims 1-3, 11, 13 and 16-17 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4-10, 12, 14-15 and 18-19 are withdrawn from further by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EP 97203974.7 on December 17, 1997. It is noted, however, that applicant has not filed a certified copy of the EP 97203974.7 application as required by 35 U.S.C. 119(b).

Specification

3. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

4. The specification is objected to because of the following informalities: page 4, line 22 recite "Eisenia foetida" the genus and species of each microorganism should be italicized. The specification should be reviewed for the above type of informalities and correction is required.

5. The specification is objected to because of the following informalities: What appear to be typographical errors. For example, page 17, line 13 "utilises" should be changed to "utilizes". The specification should be reviewed for typographical errors and correction is required.

6. The specification is objected to because it contains nucleotide and protein sequences that are not identified. For example, page 18 or page 20. These unidentified sequences occur throughout the specification. Appropriate sequence

identifiers should be used to comply with sequence rules. The sequences in the specification should match the sequence listing and computer readable form (CRF) submitted with the application. Correction is required.

Claim Rejections - 35 USC § 112

7. Claims 1-3, 11, 13 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is enabling only for the peptides of SEQ ID NO:1 which actually have trypanolytic activity, as disclosed in the specification. Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

The specification states "that SEQ ID NO:1 comprising 13 amino acids shows essential cytolytic, trypanolytic and glucan-binding characteristics comparable to the whole protein" (page 10). The specification further states " that the peptide termed CCF-1/TIP (represented by SEQ ID NO:1, the trypanolytic domain) was tested in a trypanolytic assay and was found to be trypanolytic in a time and dose-dependent way"

(page 17 and Figure 1). The specification does not disclose whether or not SEQ ID NO:3 or fragments or epitopes thereof have cytolytic or trypanolytic activity.

Therefore the specification fails to provide guidance regarding as to whether the peptides comprising SEQ ID NO:3 or fragments or epitopes thereof have cytolytic or trypanolytic activity. One of skill in the art would require guidance, in order to make or use the peptides comprising SEQ ID NO:3 or fragments or epitopes thereof in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2, 11, 13 and 16-17 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a functional fragment thereof".
It is unclear as to what the applicant is referring? Thus, the metes and bounds of "functional fragment thereof" cannot be ascertained. Clarification as to the meaning of this term is required.

9. Claims 11, 16 and 17 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims.

Claims 11 and 16-17 are drawn to a pharmaceutical composition which only contains a peptide. It is unclear as to what Applicant intends by "composition" because no pharmaceutical carrier is contained in the composition. Clarification is requested in order to overcome this rejection.

10. Claims 11 and 16-17 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "an epitope thereof".
It is unclear as to what the applicant is referring? Thus, the metes and bounds of epitope cannot be ascertained. Clarification as to the meaning of this term is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2 are rejected under 35 U.S.C. 102(a) as anticipated by Beschin et al *(The Journal of Biological Chemistry, Volume 273, Number 38, September 18, 1998, p. 24948-24954).*

Claims 1-2 are drawn to a peptide comprising at least 9 contiguous amino acids of SEQ ID No:1, comprising the amino acid sequence of SEQ ID NO:3 or functional fragment thereof wherein the said peptide is trypanolytic.

Beschin et al teach a glucan-binding and lipopolysaccharide-binding protein from *Eisenia foetida* earthworm which comprises the peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1 and the peptide of SEQ ID NO:3 involved in the activation of prophenoloxidase cascade which is designed cytolytic factor 1 or CCF Beschin et al suggest that the 42-kDa CCF-1 protein of *Eisenia foetida* coelomic fluid plays a role in the protection of earthworms against microbes (see the Abstract). The peptide/polypeptide of Beschin, et al is the same as the claimed peptide.

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e.,that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claims 1-3 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Bilej et al *(European Cytokine Network, March-April 1994, Vol. 5, No. 2, p. 99).*

Claims 1-3 and 13 are drawn to a peptide comprising at least 9 contiguous amino acids of SEQ ID No:1, comprising the amino acid sequence of SEQ ID NO:3 or functional fragment thereof wherein the said peptide is trypanolytic.

Bilej et al teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity. Bilej et al teach that the coelomic fluid of the earthworm contains strong proteolytic, hemolytic, bacteriolytic and cytolytic factors and may be an ancestral form of TNF-α. It would be inherent that the CCF-1 protein as taught by Bilej et al would comprise at least 9 contiguous amino acids of SEQ ID No:1 or comprise the amino acid sequence of SEQ ID NO:3 or a functional fragment thereof.

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e.,that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. Claims 11 and 16-17 are rejected under 35 U.S.C. 102(a) as anticipated by Beschin et al *(The Journal of Biological Chemistry, Volume 273, Number 38, September 18, 1998, p. 24948-24954).*

Claims 11 and 16-17 are drawn to a pharmaceutical composition comprising at least a peptide selected from the group consisting of a peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1, a peptide comprising the amino acid sequence of SEQ ID NO: 3, a fragment of either thereof, and an epitope of either thereof. The Examiner is viewing pharmaceutical composition as a composition that comprises only a peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1, a peptide comprising the amino acid sequence of SEQ ID NO: 3, a fragment of either thereof, and an epitope of either thereof.

Beschin et al teach a composition comprising coelomic fluid or a recombinant CCF-1 which comprises at least 9 contiguous amino acids of SEQ ID NO:1 and a peptide comprising the amino acid sequence of SEQ ID NO: 3. The composition of Beschin et al is the same as the claimed pharmaceutical compostion (p. 24949).

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e.,that the pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

14. Claims 11 and 16-17 are rejected under 35 U.S.C. 102(b) as anticipated by Bilej et al *(Immunology Letters, 45, 1995, p. 123-128).*

Claims 11 and 16-17 are drawn to a pharmaceutical composition comprising at least a peptide selected from the group consisting of a peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1, a peptide comprising the amino acid sequence of SEQ ID NO: 3, a fragment of either thereof, and an epitope of either thereof.

Bilej et al teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice (see page 124). The composition of Bilej et al is the same as the claimed invention. It would be inherent that the concentrated coelomic fluid sample would contain a peptide comprising at least 9 contiguous amino acids of SEQ ID NO:1 or a peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment/epitope of either thereof.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e.,that the pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(Lassegues et al, Euro. J. Biochem., 246:756-762 and Lucas et al, Science, Vol. 263, February 11, 1994, p. 814-817).*

Conclusion

17. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
October 15, 2001

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